



AMERICAN COLLEGE OF NUCLEAR PHYSICIANS

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By FedEx

November 29, 2004

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration (FDA)
5630 Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0432

Dear Sir or Madam:

On behalf of the American College of Nuclear Physicians (ACNP), I write to express ACNP's concern over the January 16, 2005 deadline for comments on the RDRC meeting on Radioactive Drugs for Certain Research Uses, which was held at the FDA on November 16, 2004, and at which I both a presenter and a representative of the ACNP.

We were made aware at the November 16 RDRC meeting that the FDA expects to issue a "Screening IND Guidance Draft" within the same January 16, 2005 timeframe as the comments are due. As was pointed out during the November 16 RDRC meeting, the Screening IND Guidance Draft document could materially affect the RDRC issues under discussion and up for comment by January 16, 2005. For this reason, we believe that it is important that the January 16, 2005 deadline for comments be extended, and feel that a prudent extension of such deadline should be between six and eight weeks from the time that the Screening IND Guidance Draft document is actually released.

Thank you in advance in for your consideration. With best regards,

Sincerely,

Terence M. Bevin, M.D.
Chair – ACNP Joint Government Relations Committee

cc: George Mills, M.D. – CDER

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